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April 13, 2021

VIA CM/ECF

Honorable Thomas I. Vanaskie, Special Master
Stevens & Lee, P.C.
1500 Market Street, East Tower, 18th Floor
Philadelphia, Pennsylvania 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*,
No. 1:19-md-02875-RBK-JS (D.N.J.)

Dear Judge Vanaskie:

Plaintiffs respectfully submit this letter summarizing the issues in advance of the upcoming
April 14, 2021 status conference.

1. Hetero Discovery Deficiencies

Since the status conference on March 31, 2021, Hetero has made two additional
productions available just today, but has not provided any additional responses to Plaintiffs'
queries.

As outlined in a letter sent to Hetero on March 29, 2021, Hetero was still missing key
versions of numerous quality system manuals, SOPs, site master files, Master SOP indexes, and
testing documents, despite multiple supplemental productions. Plaintiffs are in the process of
loading Hetero's new productions to evaluate which, if any, of these issues have been corrected,

Hon. Thomas I. Vanaskie, Special Master
April 13, 2021
Page 2

but without a written response to Plaintiffs' March 29, 2021 letter, Plaintiffs are left to guess at this point.

Further, Hetero still has not produced documents related to the drafting, editing, modification, distribution, and implementation of any of the quality systems manuals, testing documents, and SOPs Hetero has produced. Hetero states that when revisions are proposed for an SOP by a department within each Unit, the QA department for the Unit places the SOP in a shared folder, and then edits and revisions are made to the SOP until finalized, then a paper copy is circulated to the heads of stakeholder departments for any further edits, and then a master copy is signed. Plaintiffs have not received any documents evidencing a request for revisions, nor any draft versions of SOPs either during the electronic or manual editing process. Similarly, Plaintiffs have not received any revision requests or drafts of the quality systems manuals and testing documents.

Hetero still has not produced a list of the applications, databases, sharepoints, and other central document and data locations that contained the relevant documents and data, despite its agreement to do so weeks ago. It has only described in very general terms that each Unit has their own de-centralized server, but that is not enough. For example, Hetero has not identified the types of equipment and software used to conduct testing, nor how that testing data is stored or kept, and what was done to retrieve and produce such data. Judge Schneider required each set of manufacturer and finished dose defendants sit for an approximately two-hour in-person ESI interview back in November 2019 in order to determine this type of information. Hetero's India entities, however, did not provide information at that time because they had not appeared in the litigation due to the time delays related to Hague service, and Hetero's USA entities that did appear claimed to have no information concerning Hetero's India entities. Unfortunately, that lack of

Hon. Thomas I. Vanaskie, Special Master
April 13, 2021
Page 3

participation has led to significantly incomplete data regarding Hetero's document policies and sources of data. Plaintiffs request that Hetero now fully answer the questions that were posed to defendants during that interview.

Just before the last status conference, Hetero produced what it identified as batch records and certificates of analysis, which are categories of documents that should have been produced months ago. While Plaintiffs appreciate Hetero's production of these additional documents, this further adds to Plaintiffs' concern that Hetero's production has been incomplete. Hetero stated in its letter that it discovered "that all Batch records were not produced" in Hetero's ESI production, and then adds "[a]lthough Plaintiffs have not raised this concern, in the interest of full disclosure . . . intend to produce same to Plaintiffs." Plaintiffs are concerned at this statement, because *how were Plaintiffs to know that these batch records were missing in order to raise this as a concern?* There was no way for Plaintiffs to have known Hetero's production of batch records was incomplete in order to raise it as an issue. Thus, it raises the question, *are there other sets of documents that are either incomplete, or entire categories of relevant documents that have not been produced that Plaintiffs do not even know about?*

As Plaintiffs review the documents Hetero has now produced, we are finding evidence of more documents that are clearly relevant, and clearly missing. For example, as Plaintiffs have now discovered, Hetero was supposed to have conducted internal audits either every three months or every year, depending on the specific audit, and that presentations were made with regard to internal audits. However, Plaintiffs have only been able to locate a total of three internal audits, and no presentations concerning audits.¹ These are documents that are clearly responsive to

¹ It appears from the production log that some audit documents were produced in the new production received today, however, it takes time for Plaintiffs' vendor to process and load the

Hon. Thomas I. Vanaskie, Special Master
April 13, 2021
Page 4

Plaintiffs' document requests, yet Plaintiffs are only discovering even their existence now as a result of Hetero's production. Plaintiffs have further now identified that there are numerous Annual Product Reviews for which they have drafts, but where there is no identification of a final document. This pattern of Hetero failing to produce responsive documents, or even entire categories of responsive documents, unless specifically found as missing and identified to Hetero by Plaintiffs has been playing out for months now. This is of enormous concern as it is certain that Plaintiffs are incapable of identifying all missing documents due to the fact that they do not know the full extent of what exists, as evidenced by the production of missing batch records. It is not Plaintiffs' responsibility to specifically identify individual responsive documents, it is Hetero's responsibility to properly and fully respond to Plaintiffs' document requests. Hetero clearly has not met its obligations, and yet, Hetero has now complained that Plaintiffs continue to identify missing documents on an ongoing basis. This is a problem of Hetero's making, but, unfortunately, it is Plaintiffs' who are being prejudiced by Hetero's failure.

Finally, as noted previously, it also now appears that some custodians and witnesses were never issued litigation holds, including Venkata Pravin Kumar Penubaka, Panchakshari Nanyappa Gowda; Dr. B.V. Ramireddy, Yogeswar Reddy Mamilla, Mohan Reddy Chilukurri, Bandaru Venkata Ramarao ("B.V. Ramarao"), and Dr. Murali Nagabelli, all of whom are expected deponents.

Hetero's production continues to be deficient, and has and continues to significantly prejudiced Plaintiffs' ability to proceed with depositions related to Hetero, which have now been postponed multiple times, and continue to need to be postponed due to Hetero's failure to have

production, and for Plaintiffs to review the production, so it is unlikely Plaintiffs will know by the status conference whether or not that production is complete.

Hon. Thomas I. Vanaskie, Special Master
April 13, 2021
Page 5

actually completed its production in November 2020, when it represented to the Court that its document production was substantially complete.

2. Retail Pharmacy and Wholesaler Discovery

At the CMC on March 10, 2021, Special Master Vanaskie directed Plaintiffs to respond to Retail Pharmacy Defendants' February 16, 2021 letter (in which they asked to "pause" discovery of them), and to follow-up separately with Wholesaler Defendants as well (who also had asked to pause discovery and, at the CMC, adopted the discovery positions set forth in Retail Pharmacy Defendants' letter). Plaintiffs sent letters to each group two days after that CMC, on March 12, 2021.

Retail Pharmacy Defendants responded two weeks later via letter dated March 24, 2021. Subsequently, Plaintiffs and Retail Pharmacy Defendants had a meet and confer teleconference on April 9, 2021. The parties have made some progress on the wording of a couple of document requests, specifically those regarding inventory management policies and organizational charts. For others – specifically, those concerning (i) warranties/representations, (ii) agreements for purchase or sale of valsartan, and (iii) intra-defendant communications about the purchase or recall of valsartan – Retail Pharmacy Defendants claim the requests "should be tabled until the pleadings are more certain." Plaintiffs disagree. Judge Kugler already denied Retail Pharmacy Defendants' motion to dismiss as to at least some claims (e.g., unjust enrichment). Thus, Plaintiffs' case against Retail Pharmacy Defendants is proceeding afoot, whether or not Judge Kugler grants Plaintiffs' motion for leave to amend the master complaints as to certain claims that were previously dismissed without prejudice but with leave to amend. This draft discovery was served by Plaintiffs on December 8, 2020, when defendants' motions to dismiss were pending, and no stay of this discovery was entered or even contemplated. Now, five months later, Retail Pharmacy Defendants

Hon. Thomas I. Vanaskie, Special Master
April 13, 2021
Page 6

argue once again that discovery of party-defendants should be “tabled.” Plaintiffs seek the Special Master’s guidance (e.g., a schedule for when disputes can be raised with Your Honor) on Retail Pharmacy Defendants’ latest bite at the apple to stay or “pause” discovery. Relatedly, Retail Pharmacy Defendants raise a number of substantive objections – duplication, burden, relevance – to a draft request seeking intra-defendant communications about valsartan purchases or recalls. Plaintiffs believe this narrow request plainly seeks discoverable information, and seeks the Special Master’s guidance on how to resolve these proposed objections.

As to Wholesaler Defendants, they responded via email on March 23, 2021 to Plaintiffs’ March 12 letter. Wholesaler Defendants propose deletion of any requests for warranties/representations, agreements relating to the sale or purchase of valsartan, and a few other requests seeking inventory management information. The parties had a meet and confer on April 13, 2021. Assuming the parties cannot fully resolve all issues between them, Plaintiffs seek the Special Master’s guidance on how and when any impasses can be raised before Your Honor. Again, as with the discovery aimed at Retail Pharmacy Defendants, Plaintiffs emphasize they served this draft discovery over five months ago on December 8, 2020, and as of yet have not been able to finalize (let alone propound and receive the documents responsive to) that discovery.

3. Bellwether Plaintiff Deposition Scheduling

Plaintiffs will be prepared to discuss this issue at tomorrow's status conference.

4. Non-Responsive Document Challenges

During the last hearing with the Court, Plaintiffs provided a potential framework for expediting challenges to documents which Defendants have withheld on the basis of being non-responsive. On Monday April 12, 2021, Defendants submitted a written proposal to Plaintiffs for the mechanics and/or limitations of such challenges. Plaintiffs are in the process of reviewing the

Hon. Thomas I. Vanaskie, Special Master

April 13, 2021

Page 7

proposal with all relevant team members, and will meet-and-confer with Defendants in the coming days. Plaintiffs are hopeful that they can reach agreement with the Defendants on a mechanism and process for efficiently challenging these documents in advance of depositions without further involvement of the Court.

5. Timing of Defendants' Response to Plaintiffs' Motion for Leave to Amend

The Parties are currently meeting and conferring on the timing and length limitations for Defendants' response to Plaintiffs' motion for leave to amend.

Thank you for your courtesies and consideration.

Respectfully,



ADAM M. SLATER

cc: All Counsel (via CM/ECF)